

HEALTH LAW FOCUS

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NEW SAFE HARBOR FINALIZED

By: James T. Carroll

I. Background

Health care providers in a position to make referrals of patients or other business must consider the potential application of the federal and state antifraud statutes when entering into business relationships. Among the most important of these statutes is the Federal Antifraud Statute, which prohibits the offer, payment, solicitation or receipt of any remuneration in connection with the referral of patients or other business for which payment may be made by the Medicare or Medicaid programs. The potentially applicable penalties for violation of the Antifraud Statute are very severe, including criminal felony convictions with long prison terms and very large fines, civil exclusion from the Medicare and Medicaid programs, the imposition of civil monetary penalties

which are often very significant, and other civil consequences. Because the Antifraud Statute is very broadly worded, Congress directed the Office of Inspector General of the Department of Health and Human Services ("OIG") to promulgate so-called "safe harbor" regulations. The safe harbor regulations specify payment and business practices which, although they may fall within the very broad language of the Antifraud Statute, will not serve as the basis for criminal prosecution or a civil exclusion action under the Antifraud Statute.

II. Additional Final Safe Harbors

On November 19, 1999, the OIG published eight additional final safe harbors, seven of which were first proposed in 1993 and 1994. The major provisions of those seven final safe harbors are summarized below. The eighth new safe harbor relates to shared risk arrangements and is the subject of a separate article (see pg. 4).

In commentary accompanying the new safe harbors, the OIG noted that although many commentators requested that the safe harbors conform to the Stark Law, the two laws remain distinct. The OIG stated that the Stark Law is a civil law that does not require intent as an element, whereas the Antifraud Statute is an intent-based criminal statute. The OIG also reiterated its position that an arrangement is not necessarily illegal under the Antifraud Statute simply because it does not fit within a safe harbor, and that such arrangements would be evaluated on a case by case basis.

1. *Investments in Underserved Areas.* The final safe harbor for investments in underserved areas protects payments from investments (e.g., dividends) in entities located in urban underserved areas as well as rural underserved areas. When the safe harbor was proposed in 1993, only payments from investments in entities located in rural underserved areas were protected.

NOTEWORTHY

On June 7, 2000, the Department of Health and Human Services' Office of Inspector General ("OIG") issued draft compliance program guidance for individual and small group physician practices. The Chief Counsel to the OIG also recommends that large physician groups study the guidance. The draft guidance is intended to assist physician practices in developing compliance programs, which may in turn mitigate administrative sanctions or criminal penalties imposed on physician groups for non-compliance with federal law. The draft guidance discusses potential areas of risk involving erroneous or fraudulent conduct which the OIG has identified as potentially affecting physicians. In addition, the draft guidance indicates that physician groups should tailor compliance programs to their practices. To assist in tailoring compliance programs, the draft guidance identifies specific issues which concern physician groups, including physicians' roles in the federal Anti-Dumping Statute (affecting emergency services), gainsharing arrangements with hospitals, third-party billing practices, and professional courtesy services. The draft guidance also offers suggestions for developing a compliance program, including outsourcing all or part of a group's compliance functions. The Department of Health and Human Services published the draft guidance in the *Federal Register* on June 12, 2000 (63 Fed. Reg. 36,818 (2000)) and is accepting comments on the draft guidance until July 27, 2000. The draft guidance is also available at the OIG's website: <http://www.hhs.gov/oig/new.html>.

IN THIS ISSUE

New Safe Harbor Finalized	1
OIG Issues Anti-Kickback Safe Harbors for Shared Risk Arrangements	4
Nonprofit Joint Ventures after <i>Redlands</i>	7

This safe harbor requires satisfaction of the following eight standards: (i) no more than 50% of the investment interests of each class of investors may be held in the previous fiscal year or twelve-month period by investors in a position to make or influence referrals to, or generate business for, the entity, (ii) all investors, including passive investors, must be offered investment interests on the same terms, (iii) investment interests cannot be related to the volume or value of past or expected referrals, services or business generated by the investor to the entity, (iv) the ability of a passive investor to remain an investor cannot be conditioned on whether such investor is in a position to make or influence referrals to the entity, (v) the entity or any investor must not market or furnish the entity's items or services to passive investors differently than to non-investors, (vi) at all times at least 75% of the dollar value of the entity's business in the previous fiscal year or previous twelve-month period must be derived from the service of persons who reside in a Medically Underserved Area ("MUA") or who are members of a Medically Underserved Population ("MUP"), (vii) neither the entity nor any investor may loan funds to another investor for the purpose of obtaining an investment interest in the entity, and (viii) payments to investors must be directly proportional to capital invested. Notwithstanding the 50% limitation on investments by interested investors pursuant to part (i) above, there is no limit on the revenue that can be generated by referrals from such persons. An MUA is a rural or urban area designated by the Health Resources and Services Administration as having a shortage of health care services; an MUP is a population group designated as having such a shortage (such as certain migrant farmworkers or homeless populations).

2. Investment Interests in Ambulatory Surgical Centers. Under the safe harbor proposed in 1993, the OIG would have protected investment interests in ambulatory surgery centers ("ASCs") only if they were held entirely by surgeons who were in a position to referral patients directly to the ASC and themselves performed surgery on the patients they referred.

The final safe harbor protects four categories of ASCs owned by a variety of combinations of physicians, including (a) Surgeon-owned ASCs, where the physician investors are all general surgeons or surgeons engaged in the same surgical specialty (e.g., orthopedic surgeons), (b) Single-Specialty ASCs, where the physician investors are all engaged in the same medical practice specialty (e.g., gastroenterologists), (c) Multi-Specialty ASCs, where the physician investors are in different specialties (e.g., general surgeons, orthopedic surgeons and gastroenterologists), and (d) Hospital/Physician ASCs, where at least one investor is a hospital and the physician investors fall into one of the categories above. Additional investors are permissible in any of the four categories, so long as they are not employed by the ASC or

any other investor and are not in a position to make or influence referrals to the ASC or any investor.

The final safe harbor applies only to Medicare certified ASCs and does not protect an ASC located on the premises of a hospital that shares operating or recovery room space with the hospital. Any patients referred to an ASC by physician investor must be fully informed of the investor's interest in such ASC. The safe harbor is intended to protect only those ASCs that function as extensions of physician office practices. It is not intended to protect investments by physicians who refer to the ASC but do not personally perform ASC-covered procedures (e.g., primary care physicians).

In order to satisfy this safe harbor, four standards (the "four common standards") must be met irrespective of the type of ASC: (i) no investor may be afforded better investment terms based on past or anticipated referrals or services furnished to the entity, (ii) neither the entity nor any investor may loan funds to another investor for the purpose of obtaining an investment interest in the entity, (iii) payments to investors must be directly proportional to capital invested and (iv) the ASC and the physician investors must agree to treat Medicare and Medicaid patients in a non-discriminatory manner.

In addition to satisfying the four common standards, Surgeon-owned ASCs and Single-Specialty ASCs must satisfy the following two standards: (a) at least one-third of any physician investor's medical practice income for the previous fiscal year or twelve-month period must be from procedures performed by such investor, and (b) all ancillary services for Medicare and Medicaid patients performed at the ASC must be directly related to the primary procedures performed at the ASC and may not be billed separately to Medicare or Medicaid. Investors in Multi-Specialty ASCs must meet the four common standards, the two additional standards required of Surgeon-owned ASCs and Single-Specialty ASCs, and be able to demonstrate that at least one-third of the procedures performed by each physician investor for the previous fiscal year or twelve-month period were performed at the ASC.

Investors in Hospital/Physician ASCs must meet the four common standards and the following four requirements: (a) the ASC may not use space (including operating and recovery room space) located in or owned by the hospital unless leased in accordance with a lease that complies with the space rental safe harbor, nor may it use equipment owned by or services provided by the hospital unless the lease complies with the equipment rental safe harbor and the contract satisfies the personal services and management contracts safe harbor, (b) all ancillary services for Medicare and Medicaid patients performed at the ASC must be directly related to the primary procedures performed at the ASC and may not be billed

separately to Medicare or Medicaid, (c) the hospital must not include on its cost report or any claim for payment from Medicare or Medicaid any costs associated with the ASC (unless such program requires otherwise), and (d) the hospital must not be in a position to make or influence referrals directly or indirectly to the ASC or any investor. The final rule does not specify how a hospital is to assure that it is not in a position to make or influence referrals to the ASC as required in part (d) above.

3. *Investment Interests in Group Practices.* This final safe harbor would protect payments to a physician for his or her ownership interest in a group practice if the following four standards are met: (i) equity interests in the group practice are held by licensed health care professionals who practice in the group, (ii) the equity interests are in the group itself (and not in some subdivision thereof), (iii) the group practice meets the definition of group practice in the Stark Law and implementing regulations, and the group practice is a unified business with centralized decision making, pooling of expenses and revenues and a compensation distribution system that is not based on satellite offices operating as if they are separate profit centers, and (iv) revenues from "in-office ancillary services" meet that definition in the Stark Law.

This final safe harbor does not protect ownership by a hospital or other corporate entity, even though the Stark Law allows ownership by non-physicians. Unlike other investment safe harbors, however, the group practice safe harbor allows the practice or other group members to loan money to physician to invest in the group practice, as it is a common practice.

4. *Practitioner Recruitment in Underserved Areas.* The fourth final safe harbor would protect certain payments and other benefits offered to induce a practitioner to locate his or her primary place of practice to urban underserved areas or rural underserved areas (only rural underserved areas were protected under the proposed safe harbor). Under the final safe harbor, the location of the new primary practice site need not be more than 100 miles from the previous practice site and the recruiting entity no longer must be located in an underserved area (as required under the proposed safe harbor). In addition, a physician does not have to relocate his or her place of residence so long as his or her primary place of practice has changed.

The final safe harbor protects recruitment activities aimed at two types of health care providers: (i) a practitioner who has been practicing within his or her current specialty for less than one year, and (ii) a practitioner who is relocating his or her primary place of practice to the underserved area. The following nine standards must be met to satisfy this safe harbor: (i) the arrangement must be in writing, (ii) at

least 75% of the revenue of the new practice must be generated from patients not seen at the former site, (iii) the payments or benefits provided cannot extend beyond three years unless the practitioner's new primary place of practice is in a health professional shortage area ("HPSA") for the practitioner's specialty during the entire duration of any payments or benefits provided, (iv) recruitment benefits cannot be conditioned on referrals to or business generated for the recruiting entity, (v) the practitioner must be free to establish staff privileges at other entities and refer business to other entities, (vi) the benefits cannot be varied, adjusted or renegotiated based on the volume of business referred or otherwise generated for the entity, (vii) the practitioner must treat Medicare and Medicaid patients in a non-discriminatory manner, (viii) at least 75% of the revenue of the practice must come from patients residing in a HPSA or a MUA, and (ix) the payments cannot directly or indirectly benefit any person or entity (other than the recruited physician) who is in a position to make or influence referrals covered by the Medicare or Medicaid program.

The new part (ix) means that joint recruitment efforts with established group practices will not be covered by the physician recruitment safe harbor, nor will payments to retain physicians be protected under the safe harbor. The OIG specifically noted in the preamble to the final safe harbors, however, that joint recruitment efforts between hospitals and group practices can be efficient and cost effective, and that they are not deemed illegal simply because they do not fall within the safe harbor.

5. *Obstetrical Malpractice Insurance Subsidies in Underserved Areas.* This final safe harbor would permit a hospital or other entity to pay all or part of the malpractice insurance premiums of practitioners, including physicians and certified nurse-midwives, engaged in obstetrical practice as a routine part of his or her medical practice in a primary care HPSA.

In order for the payments to be protected under this safe harbor, seven requirements must be met: (i) the agreement to make such payments must be in writing and specify the amount and terms under which such payments will be made, (ii) for the initial period (up to one year), the practitioner must believe that 75% of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance will reside in a HPSA or MUA, or be a part of a MUP, (iii) for each additional period of coverage, at least 75% of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance must reside in a HPSA or MUA, or be a part of a MUP, (iv) the practitioner must be free to establish privileges at, refer patients to, or otherwise generate business for other entities, (v) the payment amount may not vary based on referrals, (vi) the practitioner must provide care to Medicare and Medicaid obstetrical patients in a non-

discriminatory manner, and (vii) the malpractice insurance must be provided under a bona fide insurance policy where the insurance premium, if any, is based on a bona fide assessment of the liability risk covered under the insurance policy.

6. *Referral Agreements for Specialty Services.* The sixth final safe harbor protects arrangements under which one party agrees to refer a patient to another individual or entity for specialty services in return for a promise that the patient will be referred back at a certain time or under certain circumstances. One example provided by the OIG is where a primary care physician and a specialist agree that when a patient reaches a particular stage of recovery the primary care physician will resume treatment of the patient.

The four standards required to meet this safe harbor are: (i) the mutually agreed upon time or circumstance for referring the patient back is clinically appropriate, (ii) the service for which the referral is made must not be within the medical expertise of the referring individual or entity, but must be within the special expertise of the party receiving the referral, (iii) no payment is made among the parties for the referral (and such parties do not share or split a global fee from Medicare or Medicaid for such patients), and (iv) except where both parties belong to the same physician group practice, the only exchange of value between the parties is remuneration received directly from third-party payors or the patient compensating each party for the services he or she has respectively furnished.

7. *Cooperative Hospital Service Organizations.* The seventh final safe harbor protects (i) payments from a patron-hospital to a cooperative hospital service organization ("CHSO") to support the CHSO's bona fide operational costs, and (ii) those payments from CHSOs to patron-hospitals for the purpose of paying a distribution of net earnings as required under IRS rules.

III. Modified Safe Harbor

1. *Sale of Practice.* On November 19, the OIG also modified the existing sale of practice safe harbor. The OIG expanded the sale of practice safe harbor to protect practice acquisitions by hospitals or other entities, in addition to practice acquisitions by individual practitioners, from retiring physicians in an underserved area.

A practitioner may buy the practice of another physician if (i) the sale is completed within one year from the date of the first agreement pertaining to the sale, and (ii) the selling physician will not be in a position to make referrals to or generate business for the purchasing physician after that one year period.

The purchase of a practice of a physician by a hospital or other entity will fall within the safe harbor only if the following four standards are met: (i) the sale is completed within three years from the date of the first agreement pertaining to the sale; (ii) the selling practitioner will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing hospital or entity; (iii) the practice being acquired is in a HPSA for the practitioner's specialty; and (iv) commencing at the time of the first agreement pertaining to the sale, the hospital or entity must diligently and in good faith begin commercially reasonable recruitment efforts to obtain a new practitioner to take over the acquired practice within one year pursuant to an arrangement that meets the practitioner recruitment safe harbor.

The final safe harbors published on November 19, 1999 expand the protected payment and business practices excluded from criminal prosecution or a civil exclusion under the Antifraud Statute. Providers must take these final safe harbors into account when engaging in any transactions of the nature described above. In addition, providers should update their compliance plans to incorporate the final safe harbors.

OIG ISSUES ANTI-KICKBACK SAFE HARBORS FOR SHARED RISK ARRANGEMENTS

The Department of Health and Human Services ("Department") Office of Inspector General ("OIG") recently issued an interim final rule setting forth two new safe harbors from the federal Anti-Kickback Statute (section 1128B(b) of the Social Security Act) applicable to shared risk arrangements (the "Shared Risk Safe Harbors"). See 64 Fed. Reg. 63504. The first of the Shared Risk Safe Harbors protects certain financial arrangements between a

NOTEWORTHY

On June 13, 2000, a three-judge panel of the U.S. Court of Appeals for the Tenth Circuit reinstated the conviction of former Kansas City hospital executive Dennis McClatchey, one of the defendants in the well-publicized *Anderson* case. In April 1999, two hospital administrators and two physicians in that case were sentenced to prison for their roles in an alleged kickback scheme, including allegations of overpayment for consulting services that were not provided. The trial court judge then overturned the conviction of Mr. McClatchey on the basis of insufficient evidence of illegal intent. The Tenth Circuit's unanimous opinion found that there was sufficient evidence of specific intent to violate the statute to support a conviction because the government had proven that the remuneration was paid at least in part to induce referrals.

managed care plan and a health care provider/contractor where the plan is an "eligible managed care organization" compensated on a capitated or fixed prepaid basis by a federal health care program. The second safe harbor protects certain financial arrangements between a managed care plan and a health care provider/contractor where the provider/contractor is placed at substantial risk for the cost or utilization of items or services furnished to federal health care program beneficiaries. These safe harbors implement and expand the statutory exception to the Anti-Kickback Statute enacted in section 216 of the Health Insurance Portability and Accountability Act of 1996.

Background

Generally speaking, the Anti-Kickback Statute prohibits any person from knowingly and willfully offering, paying, soliciting or receiving, anything of value to influence the referral of business that is reimbursed under a federal health care program, including Medicare and Medicaid. Violation can result in conviction of a felony, punishable by up to five years in prison, criminal fines of up to \$25,000, administrative civil monetary penalties of up to \$50,000 or exclusion from participation in federal health care programs.

Because of the breadth of the Anti-Kickback Statute, the Department is authorized to identify as "safe harbors" those payment and business practices which, though potentially prohibited by the law, will not be prosecuted under the Anti-Kickback Statute. Compliance with a safe harbor is voluntary and the failure to fit squarely within a safe harbor does not necessarily mean that an arrangement is illegal. Arrangements that do not fit squarely within a safe harbor, however, are subject to greater scrutiny and will be analyzed on a case-by-case basis.

Managed care plan arrangements with health care providers may implicate the Anti-Kickback Statute because many such arrangements typically offer providers the promise of increased patient volume if the provider will grant the plan a substantial discount on its fees. Thus, the provider is providing the plan with remuneration in the form of a discount in exchange for receiving increased patient volume. Where those patients are enrolled in a federal health care program, the Anti-Kickback Statute is implicated.

New Shared Risk Safe Harbors

The new Shared Risk Safe Harbors protect certain arrangements where, *and only where*, the remuneration received for purposes of the Anti-Kickback Statute is a price concession (*i.e.*, discount) granted in exchange for the provision of health care services or items. Arrangements involving other forms of remuneration are not covered by the Shared Risk Safe Harbors, although they may qualify for protection under other safe harbors promulgated previously.

It is important to note that the Shared Risk Safe Harbors apply only in the context of health care items, devices, supplies and

services and reasonably related services such as non-emergency transportation, patient education, attendant services, social services, utilization review and quality assurance. The Shared Risk Safe Harbors do not apply to protect payments made in exchange for other items and services such as marketing or other pre-enrollment activities.

It also is important to note that, in the interim final rule, the OIG takes the position that if an arrangement that includes both remuneration that qualifies under either of the Shared Risk Safe Harbors, and remuneration that does not qualify for protection, the former remains protected, and the latter would be scrutinized on a case-by-case basis to determine whether it violates the Anti-Kickback Statute. Thus, protected remuneration does not lose its protected status when coupled with remuneration that does not qualify for protection.

Price Reductions Offered to Eligible Managed Care Organizations

The first of the two new Shared Risk Safe Harbors protects payments between an "eligible managed care organization" and a health care provider directly contracted by the organization (*i.e.*, a "first tier contractor") so long as the following conditions are met:

1. the payments are made in exchange for the provider providing or arranging for the provision of health care items or services;
2. the payments are made pursuant to a written agreement executed by the organization and the provider which specifies the covered items and services and has a term of at least one year;
3. the agreement specifies that the provider cannot claim payment directly or indirectly from any federal health care program for items/services covered under the agreement, except that (a) a provider that is a federally qualified health center may claim supplemental payments from a federal health care program, and (b) if specified in the organization's agreement with the provider, the provider may claim payment from HMOs and competitive medical plans with cost-based contracts or from federally qualified HMOs without a HCFA contract;
4. in establishing the terms of the agreement, neither party pays or receives remuneration in return for, or to induce, the provision or acceptance of business (other than the business that is the subject of the agreement) for which payment may be made, in whole or in part, by a federal health care program on a fee for service basis; and
5. neither party to the agreement shifts the financial burden of the agreement by claiming increased payments from a federal health care program (*i.e.*, there is no protection if the arrangement is implicitly or explicitly part of a broader scheme to steer fee-for-service federal health care program business to the provider).

This safe harbor similarly protects payment arrangements between a first tier contract or that holds the direct contract with the eligible managed care organization (such as a PHO) and the first tier contractor's subcontractor (*i.e.*, a "downstream" provider such as a PHO hospital) so long as:

1. there is an agreement between the two which meets the requirements specified above, except that no exceptions apply in this context that would permit the downstream provider to claim payments directly or indirectly under any circumstances from a federal health care program for items/services covered under the agreement; and

2. the "upstream" agreement between the eligible managed care organization and the first tier contractor does not involve (a) a federally qualified health center receiving supplemental payments, an HMO or competitive medical plan with a cost-based contract, or (b) a federally qualified HMO, unless the items/services are covered by a risk contract under Section 1854 or Section 1876 of the ("Act").

For purposes of this safe harbor, an "eligible managed care organization" includes any of the following:

1. an HMO or competitive medical plan with a risk or cost-based contract in accordance with Section 1876 of the Act;
2. any Medicare+Choice plan paid a capitation payment from Medicare and which must have its total Medicare beneficiary cost sharing approved under Section 1854 of the Act;
3. Section 1903(m) Medicaid managed care plans;
4. any other health plan with a risk-based contract with a state Medicaid agency;

NOTEWORTHY

The IRS has taken drastic action to enforce TBOR2 by levying substantial penalty excise taxes on disqualified persons and revoking exemption retroactively in a recent health care audit. In September and November, 1999, six nonprofit corporations in the home health industry and five individuals (the founders and their children) filed petitions in the Tax Court challenging the IRS action (*Sta-Home Home Health Agency, Inc. of Grenada, Miss., et al. v Commissioner*). As this issue goes to press, the IRS has not yet filed its response. It appears that the enforcement action relates to the sale of substantially all of the assets of the nonprofits to corporations owned by one or more of these individuals in return for an assumption of the associated liabilities and no other consideration. Even though the organization had a history of losses, the IRS apparently disregarded a supporting appraisal. Its reasons for doing so are not yet clear.

5. Programs for all Inclusive Care for the Elderly ("PACE") other than for profit demonstrations; and

6. federally qualified HMOs.

This Shared Risk Safe Harbor recognizes that when a managed care organization is paid on a prepaid fixed, or capitated, basis by a federal health care program, there is little risk to the federal health care program of overutilization or increased costs. That is, due to the nature of the payment being made to the managed care organization, the managed care organization is incented to prevent overutilization and contain costs and, in any event, the cost of services and items utilized is borne by the organization, and not a federal health care program.

Price Reductions Offered by Providers With Substantial Financial Risk

The second of the two new Shared Risk Safe Harbors is largely aimed at employer-sponsored health plans that cover retirees who may also qualify for secondary Medicare coverage. This Shared Risk Safe Harbor protects payments between a qualified managed care plan and a first tier contractor for providing or arranging for services made in accordance with the following standards:

1. there is a written agreement executed by the plan and contractor which specifies the covered items and services and has a term of at least one year;

2. the agreement must require participation in a quality assurance program that promotes the coordination of care, protects against underutilization and specifies patient goals, including measurable outcomes where appropriate;

3. the agreement specifies a payment methodology that is commercially reasonable and consistent with fair market value in an arms' length transaction and includes the intervals at which payments will be made and the formula for calculating incentives and payments, if any;

4. if the first tier contractor has an investment interest in the plan, the investment interest must meet the investment interest safe harbor;

5. the contractor must have assumed substantial financial risk for the cost or utilization of services it is obligated to provide through (a) a periodic fixed payment per patient that does not take into account the dates of service, frequency of services or extent or kind of services provided, (b) percentage of premium, (c) federal health care program DRGs or (d) qualified bonuses and withholds, or, alternatively in the case of physicians, the physician is subject to a physician incentive plan that meets the requirements set forth in the physician incentive plan regulations;

6. payments for items and services reimbursed by a federal health care program comply with the following two standards:

(a) the qualified managed care plan must submit claims directly to the federal health care program, in accordance with a valid reassignment agreement (except inpatient hospital services, other than psychiatric services, qualify if paid on a DRG basis), and (b) payments to the first tier contractor and any downstream contractor which are reimbursed by a federal health care program must be identical to payment arrangements between such parties for the same items and services provided to other beneficiaries with similar health status, except that payments may be adjusted where the adjustments are related to utilization patterns or cost of providing items or services to the relevant population;

7. in establishing the terms of the arrangement, neither party pays or receives remuneration in return for, or to induce, the provision or acceptance of business (other than the business that is the subject of the agreement) for which payment made be made, in whole or in part, by a federal health care program on a fee for service basis; and

8. neither party to the agreement shifts the financial burden of the agreement by claiming increased payments from a federal health care program.

Payments from first tier contractors to downstream contractors also are protected provided many of the same requirements are satisfied and *both* parties to the contract have assumed substantial financial risk for services and items covered by the contract.

For purposes of this Shared Risk Safe Harbor, a qualified managed care plan is a health plan that provide a comprehensive range of health services and include certain elements to assure that the health care services are managed (*i.e.*, utilization management, quality assurance and grievance procedure requirements). In addition, the plan must be at risk for services to their non-Medicare enrollees and either (a) no more than 10% of the plan's enrollees are Medicare beneficiaries, not including persons for whom a federal health care program is a secondary payor, or (b) at least 50% of the plan's enrollees must be non-federal health care program enrollees (not including persons for whom a federal health care program is the secondary payor).

Health plans and providers should review their compensation arrangements to determine the extent to which such arrangements may, or could qualify, for protection under the Shared Risk Safe Harbors. Health plans and providers that are unsure whether a particular arrangement qualifies for protection may submit a request to the OIG for an advisory opinion.

NONPROFIT JOINT VENTURES AFTER REDLANDS

By: Gerald M. Griffith

The recent Tax Court decision in *Redlands Surgical Services v. Commissioner* (July 19, 1999) may have a profound impact on a

variety of health care joint ventures involving tax-exempt hospitals and tax-exempt clinics seeking to partner with for-profit entities. In *Redlands*, the court denied exemption to a nonprofit entity participating in an ambulatory surgery center joint venture, based primarily on the 50/50 nature of governance (*i.e.*, the nonprofit's lack of outright control). Even though the ASC was this nonprofit entity's sole activity, the opinion is likely to have a significant impact on the structuring and operation of all ancillary joint ventures involving tax-exempt organizations. As a result, it is likely that nonprofits will at a minimum be more cautious in entering into such joint ventures and will need to look closely at the structure of existing joint ventures.

The key consideration in both the IRS' and the Tax Court's analysis in *Redlands* was control. Specifically who had control of the joint venture? Where the joint venture is the nonprofit's only activity, control of the joint venture is tantamount to control of the nonprofit entity itself. Control was defined as essentially including one or more of: (a) majority voting control; (b) broad day-to-day management authority; or (c) initiation rights (*e.g.*, does the exempt entity have the ability to cause the joint venture to take action to assure a community benefit or terminate the management agreement without the for-profit partner being able to block that action).

In all joint ventures, resolution of the control issue is likely to affect whether or not the exempt entity has taxable unrelated business income from the joint venture. If the joint venture also represents substantially all the charitable activities of the exempt entity, resolution of the control question is likely to be determinative for continued tax-exempt status of the entity. In deals with insiders, even if the venture involves less than all of the exempt entity's activities, allowing shared control may result in inurement triggering penalty excise taxes under TBOR2 (Section 4958 of the Internal Revenue Code) and possible loss of tax-exempt status.

It remains to be seen what informal evidence of control short of a voting majority on the board will satisfy the IRS and the courts. One possibility may be to have a 50/50 board but with initiation

NOTEWORTHY

We are proud to announce the publication of the second edition of a landmark health care legal practice guide, authored by our partner, Gerald M. Griffith. Published by the American Health Lawyers Association, the new practice guide is titled *Physician Recruitment and Retention: Reconciling Legal Tensions Between Tax Law and Fraud & Abuse, 2nd Edition*. In this version, Mr. Griffith reviews recent legal developments affecting a variety of arrangements for the recruitment and compensation of physicians by health care organizations. Copies of the second edition of the practice guide may be ordered by contacting the AHLA at (202) 833-0766 or on the web at <http://www.healthlawyers.org>.

rights such as the unilateral right for the exempt entity to terminate the management company or to expand or reconfigure services to meet a community need. It may also be possible to argue that participation in a joint venture is justifiable as an investment if there is a reasonable rate of return given the risk of the business and if the nonprofit's participation is totally passive as it would be for a typical shareholder in a publicly traded company or an investor in a real estate limited partnership. Using a taxable subsidiary also may minimize the exempt status risk as long as all arrangements with the for-profits or other insiders are structured on an arm's length, fair market value basis so as to avoid indirect inurement.

Control is relevant not just as a protection to avoid inurement, since that could be satisfied in many cases by a veto power or blocking right. Control is also relevant to show that participation in the joint venture furthers exempt purposes (a long standing requirement for nonprofit participation as a general partner in a partnership with a for-profit). Although the hospital bemoaned the capacity woes in its outpatient surgery department, there is nothing in the tax court opinion to indicate that buying into an already existing surgery center had any tangible effect on the

capacity problem in the community as opposed to an apparent shifting of cases and revenues to the ASC. Without majority control or other initiation rights, Redlands Surgical Services also could not assure itself that the ASC would take any action to expand or reconfigure services to meet community needs. It is true that revenues from the ASC could be used to fund charitable programs at the hospital which would benefit the community, but under Section 502 of the Internal Revenue Code, merely using the profits of a business to fund charitable projects does not alone make the business charitable. The IRS and the courts focus instead on how that business is operated and whether its operations are charitable. Without that "charitability," as long as everything is at fair market value the joint venture can still be operated, but its revenues (to all partners) will be fully taxable like any other business.

Some additional clarification may be provided in the pending appeal of the *Redlands* case or in future IRS private letter rulings that likely have been held up pending the outcome in *Redlands*. In the meantime, nonprofits entering into joint ventures with for-profits should tread carefully and consider the principles outlined in the *Redlands* case and other relevant guidance.

COMING ATTRACTIONS

HMS&C Attorneys frequently are asked to speak at conferences and seminars. A calendar of upcoming speaking engagements is provided below. For additional information on any of these speaking engagements, please call Lee Ann Jones at 313-465-7224.

<u>Topic</u>	<u>Date</u>	<u>Location</u>	<u>Speaker</u>
American Health Lawyers Association Emerging Trends in Healthcare Liability	June 19 and 21, 2000	Washington, D.C.	Julie E. Robertson
American Health Lawyers Association Tax Issues for Healthcare Organizations Physician Recruitment	Sept. 21-22, 2000	Miami, Florida	Gerald M. Griffith

Honigman Miller Schwartz and Cohn is a general practice law firm headquartered in Detroit, with an additional office in Lansing, Michigan. Honigman Miller's staff of more than 175 attorneys and more than 300 support personnel serves thousands of clients regionally, nationally and internationally. Our health care department includes the fifteen attorneys listed below who practice health care law on a full-time or substantially full-time basis, and a number of other attorneys who practice health care law part-time. Except as denoted below, attorneys in the health care department are licensed to practice law in the State of Michigan only.

James T. Carroll, III	William O. Hochkammer	Lynn A. Kriser	Linda S. Ross
William M. Cassetta	Renee M. Howard	Patrick LePine	Chris Rossman
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Gerald M. Griffith	Dawn R. Kreysar	Julie E. Robertson	

* Licensed to practice law in Michigan and Florida.
 § Florida board certified health law specialist.

For further information regarding any of the matters discussed in this newsletter, or a brochure that more specifically describes our practice in health care law, please feel free to contact any of the attorneys listed above at our Detroit office by calling (313) 465-7000 or our Lansing office at (517) 484-8282.

Honigman Miller Schwartz and Cohn's *Health Law Focus* is intended to provide information but not legal advice regarding any particular situation. Any reader requiring legal advice regarding a specific situation should contact an attorney. The hiring of a lawyer is an important decision that should not be based solely upon advertisements. Before you decide, ask us to send you free written information about our qualifications and experience.

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